Remarks Regarding Rejection under 35 U.S.C. § 102

Claim 19 stands rejected as allegedly anticipated by U.S. Patent No. 6,120,500 issued to Bednarek *et. al.* (hereafter "Bednarek").

The Examiner alleges that Bednarek recites an ablation catheter "wherein the distal portion has a cross-sectional configuration along the active region and the cross-sectional configuration is adapted to bias the active region against the tissue to be ablated." Office action at page 2.

Applicants have amended claim 1 to make clear that the "cross-sectional configuration has an outer periphery that is adapted to bias" the outer peripheral wall. Bednarek does not disclose a cross-sectional configuration having an outer periphery that is adapted to bias the outer peripheral wall of the catheter against the tissue to be ablated. For at least this reason, Applicants respectfully request that the Section 102 rejection of claim 19 be withdrawn.

§ 103 Rejections based on Bednarek and Takahashi

Claims 1, 8 and 19 (and all claims depending therefrom)

Claims 1, 5-9, 11, 12, 14/12 and 15-19 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bednarek in view of U.S. Patent 6,231,585 to Takahashi *et. al.* (hereafter "Takahashi"). Examiner asserts:

> Bednarek et. al. teach all of the limitations of the claims except the cross-sectional configuration including a flattened outer peripheral wall and the dimensions of the aspect ratio as claimed. Takahashi et. al. disclose a catheter and teach that it is old and well known in the art to provide a catheter with a cross-sectional perimeter of various shapes including a *flattened outer peripheral wall to stabilize the device within the treatment location.* Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the [Bednarek] catheter such that its cross sectional perimeter includes a *flattened outer peripheral wall to stabilize the device within the treatment area* as taught by Takahashi . . . . (Office action at 2-3).

Applicants respectfully disagree. Even assuming there is a motivation to combine Takahashi with Bednarek, the combination does not yield Applicants' invention. Examiner's reliance on Takahashi is misplaced because Takahashi neither teaches nor suggests a "cross-sectional configuration [that] is adapted to bias said active region against the tissue to be ablated," and therefore, the combination of references will not yield Applicants' invention.

Takahashi recites methods and devices which are directed toward stabilizing *a treatment site*, but not directed to pressing a active treatment device against tissue. For example, Takahashi teaches:

> The stabilizing of the treatment site generally includes applying a tension to the surface of the treatment site within the bodily cavity,

Remarks Regarding Rejections under 35 U.S.C. § 103

In order to "establish a prima facie case of obviousness, three basic criteria must be met." MPEP § 7.06.02(j). First, there must be some motivation or suggestion to modify the reference or to make the proposed combination. Second, there must be a reasonable expectation of success. "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure." MPEP § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Third, the combined references must teach or suggest all claim limitations.

> *which may be useful in more clearly visualizing the treatment site and/or making incisions therein*, and the like. Generally, the application of a partial vacuum and the clinging of the suction channel to the treatment site also cause partial extrusion of the treatment site through the opening defined by the ring- or horseshoe-shaped suction channel, which may also enhance visibility and lend desirable attributes to the treatment site. (Takahashi at Col. 14, lines 3-12) (emphasis added).

More particularly, Takahashi teaches that the device can be used "for stabilizing *the surface* of a treatment site." Takahashi, claim 1 (emphasis added).

The ring- or horseshoe-shaped openings of Takahashi are illustrated in Figs. 1 and 8 (56). In simple terms, the ring or horseshoe lies on the surface of a tissue and creates a treatment site in the opening (56) formed by the device. There is no teaching or suggestion in Takahashi that the tissue lying under that portion of the device that is pressed against the tissue can be treated at all. Indeed, Takahashi teaches that the opening (56) formed by the device is where treatment is to occur. See, e.g., claim 6 ("wherein *the opening* defined by the ring- or horseshoe-shape of the suction channel *is sized to allow surgical attachment therethrough* of a coronary artery bypass graft to an anastomotic site at the treatment site."); claim 13 ("light transmitted by the light port illuminates *a treatment site inside the opening*"). The opening is formed by the stabilization device—and thus, the tissue is accessible only because the device is not biased against the tissue. Where the device is biased against the tissue, the tissue is not accessible for treatment.

Thus, assuming for the sake of argument that there is a motivation to combine the teachings of Takahashi with the catheter of Bednarek, the result would be a catheter with a suction stabilization system that is located on the underside of the catheter whereas the

active region of the catheter is on the lateral edge of the catheter. The result would be that the modified catheter does not bias the tissue against the active region.

In each of Bednarek and Takahashi, the device is designed to form a loop. Takahashi would teach that when the loop is formed, the suction device is formed on the underside of the loop—or in the vernacular of Takahashi, on the underside of the "doughnut." Bednarek's catheter, however, has an active region that is on the outside edge of the "doughnut." Thus, the tissue that is biased against the "doughnut" is not in contact with the active region, and indeed, is not even accessible because it is covered by the suction stabilization system of Takahashi.

In contrast to Takahashi, Applicants' device is an ablation catheter. Applicants' claims require that the active region of the catheter be in contact with the tissue to be ablated (the "treatment site"):

- wherein said cross-sectional configuration is adapted to bias said **active region against the tissue to be ablated** and wherein said cross-sectional configuration of said active region includes a flattened outer peripheral wall. (From claim 1)

- wherein said cross-sectional configuration is adapted to bias the **outer peripheral wall of the catheter against the tissue to be ablated** in order to resist movement of the catheter relative to the tissue being treated. (From claim 19)

Applicants' claims require that the cross-sectional configuration be adapted to bias the active region or the outer peripheral wall of the catheter *against the tissue to be*

ablated. Takahashi does not teach or suggest an active region or outer peripheral wall that is adapted to bias the tissue against the active region. Indeed, the tissue which is held "against" the surface of Takahashi's device is accessible for treatment. Therefore, the combination of Bednarek and Takahashi as suggested by the Examiner fails to yield the claimed inventions. For at least these reasons, the 103 rejections must be withdrawn.

Applicants request that the rejection of claim 1, 8 and 19 under § 103 be withdrawn.

Dependent claims 5-7, 9, 11, 12, 14/12 and 15-18 are patentable for at least the same reasons that claims 1 and 8 are patentable. Accordingly, Applicants request that all of the pending claims be allowed.

Claims 7, 16, and 17

In connection with those claims that were directed to cross-sections having certain aspect ratios, the Examiner asserts that "it would have been obvious to construct the cross-section of the catheter according to the aspect ratio as claimed, since it has been held that discovering the optimum size only involves routine skill in the art." (Page 3 of the Office action). It is not clear what reference the Examiner is relying upon in making this statement. Takahashi does not address any D-shaped configurations, and so, for at least this additional reason, Applicants submit that claims 7, 16 and 17 are patentable. If Examiner is relying on another reference, or upon personal knowledge, Applicants request clarification and further request that the Examiner direct Applicants to the specific passages upon which Examiner is relying.

Claims 3, 4, 10, 13, 14/13

Claims 3, 4, 10, 13, 14/13 were previously withdrawn in response to a restriction requirement. Upon allowance of Claims 1, 8 and 19, Applicants request reconsideration of the previously withdrawn claims. These claims should be allowable for at least the reasons that claims 1, 8 and 19 are allowable.

CONCLUSION

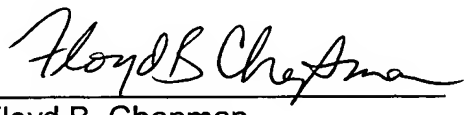
Applicants request prompt reconsideration of the pending rejections. Applicants submit that the application is in condition for allowance, and allowance of all pending claims is requested.

If there are any additional fees due with the filing of this document, including fees for the net addition of claims and/or any extension fees, the undersigned respectfully requests that any and all fees be charged to Deposit Account No. 50-1129. If any extension of time request or any petition is required for the entry of this paper or any of the accompanying papers, Applicants hereby petition or request the extension necessary. The undersigned authorizes any fee payment from Deposit Account No. 50-1129.

Respectfully submitted,

WILEY REIN & FIELDING LLP

Date: August 15, 2005

By: 

Floyd B. Chapman
Reg. No. 40,555
Andrew P. Zager
Reg. No. 48,058

WILEY REIN & FIELDING LLP
Attn: Patent Administration
1776 K Street, N.W.
Washington, D.C. 20006
Telephone: 202.719.7000
Facsimile: 202.719.7049